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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

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on September 16, 2009

Signature /glennlwebb32668/

Typed or printed name Glenn L. Webb

Application Number	Filed
10/817172	April 2, 2004
First Named Inventor	
Donald P. Bushby	
Art Unit	**Examiner**
3772	Patel

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 32668.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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September 16, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 2 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Discussion of Rejection of the Claims

Rejection of the claims under 35 USC 112, second paragraph.

Claims 45, 47, 61, 67, 69, 72, 77, 78 and 79 are rejected under 35 USC 112, second paragraph as being indefinite. As far as this rejection can be understood, the limitations of **1)** ratio of elongation to tensile strength is less than .9 and **2)** the 15% elongation when subjected to a tensile load approximately equivalent to 25 pounds were rejected as described on pages 2 – 3 of the Office Action. The rationale for this rejection is difficult to follow. The Examiner cites, among other factors, that Applicant's failure to provide examples at different tensile loads, failure to assert whether the ratio of elongation is a linear ratio, failure to assert whether or not the tear or breaking point, and failure to provide examples and data to support the claim limitations.

Claims 45, 72 and 78 have the limitation of:

"said sole member has a ratio of elongation to tensile strength (lb/in-width) that is less than 0.9 to provide a balanced combination of strength and resistance to elongation." This limitation has direct support in the originally filed specification at paragraph 0059.

As can be clearly seen in that paragraph, the claimed limitation for the ratio of elongation to tensile strength (lb/in-width) that is less than .9 is described in the specification so that one skilled in the art would understand that when considering the materials for the sole member, simply go to any materials handbook for that material, take the elongation property for that material, divide that number by the tensile strength and make sure the resulting number is less than .9. Or one skilled in the art would simply take the tensile strength, multiply it by .9 and make sure that the elongation is less than that result. Examples, data, etc. simply are not necessary for one skilled in the art to be able to select a material based on this limitation, nor has the Examiner stated a basis for requiring examples, data, etc.

Claims 47, 61, 67, 69, 77, and 79 have the limitation of:

"said stretch-resistant sole member exhibits less than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds in accordance to ASTM D3759."

These claims include a typographical error that will be corrected at the time of submitting the Appeal Brief. The limitation should not include the "(lb/in-width)". Again, paragraph 0059 of the specification clearly provides support for this limitation. One skilled in the art would

certainly be able to access ASTM D3759, conduct a test in accordance with the standards delineated by that standard, and determine whether or not a material would exhibit less than 15% elongation when subjected to a tensile load equivalent to 25 pounds in accordance with the conditions of that standard. Examples, data, etc. simply are not necessary for one skilled in the art to be able to select a material based on this limitation. One skilled in the art can easily apply the standards of the test as specified by the ASTM to determine this limitation.

103 Rejection

The claims have been repeatedly rejected under 35 USC 103 in view of combinations of Burgess, Holden, Domenico, Desnoyers, and Huddleston et al.

The limitations of each of claims 43 - 77 include an: 1) Orthotic foot support device; 2) a thin flexible stretch-resistant sole member of uniform thickness having a shape matching less than the entire outline of a sole of a wearer's foot to which the device is to be applied and sized to cover only a portion of the wearer's sole; 3) adhesive layer for securely adhering said device directly to an outer skin tissue on the sole of the foot; 4) at least one protective cover removeably disposed over the adhesive layer; 5) the stretch resistant sole member sufficiently stretch-resistant to restrict extension and stretching of an outer skin tissue on the sole of a foot when adhere thereto; and 6) the adhesive layer having sufficient adhesion to maintain the stretch resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, adhesive layer and sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia.

None of the references, taken either singly or in combination with one another disclose 1) an orthotic foot support device; 2) sizing the orthotic foot support device to cover only a portion of the wearer's sole; 3) a stretch-resistant material to restrict extension and stretching of an outer skin tissue; or 4) an adhesive layer having sufficient adhesion to restrict extension and stretching of an outer skin tissue of a foot to prevent excessive tensile stress in a plantar fascia.

Orthotic device for providing support to and reducing stress on the plantar fascia of a human foot

The Office Action states that "Burgess discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot." This statement has absolutely no support in the disclosure of Burgess who does not even discuss orthotic

devices or plantar fascia. Burgess discloses a disposable foot protector for protecting the sole of a foot from surfaces of indeterminate cleanliness and temperature fluctuations. Burgess does not disclose, discuss or suggest an orthotic device for treating the plantar fascia by minimizing tensile forces on the plantar fascia.

Sole member sized to fit only a portion of the wearer's foot.

The Office Action acknowledges that Burgess does not disclose this limitation, but that since Holden discloses a foot protector that can be cut to fit less than the sole of the foot, it would be obvious to combine the references to arrive at this limitation. To do so would render the device of Burgess ineffective for it's stated purpose. The device of Burgess is intended to protect the wearer's foot from surfaces of indeterminate cleanliness and temperature fluctuations. To alter the size or shape of Burgess to cover less than the entire sole of the foot would expose other uncovered portions of the sole to the very surfaces intended to be protected by the device. One skilled in the art would not consider this combination as suggested by the Office Action. This presently claimed limitation enables the plantar fascia to be effectively treated while continuing to comfortably wear shoes and hose without undue interference.

Stretch-resistant sole member that restricts the extension and stretching of an outer skin tissue on the sole of the foot.

The only point of rejection in the Office Action directed to this limitation was to place the phrase "stretch-resistant" in quote marks (paragraph 5, line 5) and to make a conclusionary statement with no rationale at continuing paragraph at the top of page 4

Burgess discloses that the disposable foot protector of Burgess further is **sufficiently flexible to allow increased mobility as it is able to adjust to flexing of the foot during normal walking or running movements without inhibiting foot movement** or causing the tack adhesive to tear away from the foot. column 3, lines 46 – 50. The disposable foot protector of Burgess is clearly not intended to restrict the extension of the outer skin tissue of the foot, particularly not to minimize tensile forces on the effectively inelastic plantar fascia.

Adhesive layer having sufficient adhesion to maintain the stretch resistant sole member in adhesive engagement with an outer skin tissue on the sole of the foot, such that tension forces applied to a plantar fascia are shared with an outer skin tissue, adhesive layer and sole member to restrict extension and stretching of an outer skin tissue of a sole of a wearer's foot, whereby preventing excessive tensile stress in a plantar fascia.

The Office Action rejected this limitation at the second full paragraph of page 5. It is unclear as to what the Examiner is referring to as paragraphs 0016 and 0027, as none of the references or Applicant's specification match up with these statements. Regardless, none of the references discuss using an adhesive layer with sufficient adhesion so that the tension forces applied to the plantar fascia are shared with the outer skin tissue, adhesive layer and sole member to restrict extension and stretching of the outer skin tissue to prevent excessive tensile stress in the plantar fascia. Instead Burgess discloses using low tack adhesives for ease of movement of the user's foot, to allow flexibility of movement and at column 3, lines 56 – 60, to allow increased mobility as the foot protector is able to adjust to flexing of the foot during normal walking or running movements **without inhibiting foot movement**. Burgess discloses that the foot protector, should be **soft and flexible so that it feels more like a soft house slipper than a shoe or sandal** and that the adhesion should only be sufficiently strong so that it will not fall off. column 4, lines 17 – 25. Neither Burgess, nor any of the cited references discuss using a strong adhesive to ensure that the tensile forces on the plantar fascia are minimized by sharing the forces with the sole member, adhesive and outer skin tissue.

Uniform thickness of less than 30 mils

Claims 46, 68, 69, and 74 include the limitation that the sole member has a thickness of less than 30 mils (.0762 mm). Burgess discloses a foot protector that has a thickness between about 1 mm to 5 mm. The Office Action has expanded the scope of that range to cover an additional 25% to encompass this limitation, despite the disclosure of Burgess that the layer should be sufficiently thick to provide cushioning. Burgess clearly does not disclose making it's cushioned foot protector thinner than the disclosed range as to do so would render it ineffective.

Ratio of elongation to tensile strength (lb/in-width) that is less than 0.9 to provide a balanced combination of strength and resistance to elongation

Claims 45, 72, and 78 have this limitation that sets the range for the stretch resistant characteristic of the claimed invention. The Office Action alleges that Desnoyers teaches this limitation and that it would be obvious to combine the tape of Desnoyers with the foot protector of Burgess to arrive at the claimed invention. However, Desnoyers does not disclose this limitation. ***Desnoyers does not discuss a ratio of elongation to tensile strength,*** but instead discloses at column 3, lines 20 – 26 that the ***ratio of elongation in the lengthwise direction to the elongation in the crosswise direction*** being 10 to 1 and the ***ratio of tensile strength in the***

lengthwise direction to the tensile strength in the crosswise direction to be about 3 to 1. ***Desnoyers does not discuss any ratio of elongation to tensile strength.***

Stretch-resistant sole member exhibits less than 15% elongation when subjected to a tensile load approximately equivalent to 25 pounds in accordance to ASTM D3759.

Claims 47, 61, 67, 69, 77, and 79 include this limitation. Please note the typographical error of describing the 25 pound limitation as 25 pounds/inch. The claims will be amended with the submission of the Appeal Brief to correct this typographical error. The Office Action stated that Huddleston et al. discloses this limitation and that it would have been obvious to combine this disclosure with Burgess to arrive at the claimed invention. Huddleston discloses an aluminum metal tape for use with fiberglass air ducts that has an average tensile strength of not less than 25 pounds per inch. ***However, Huddleston et al. does not disclose the percentage of elongation when subjected to a tensile load of 25 lbs. There is no disclosure in any of the references of a material having the limitation of less than 15% elongation when subjected to a tensile load approximately equivalent to 25 pounds in accordance to ASTM D3759.*** It can not be considered obvious to modify Burgess to include this limitation when there is no suggestion anywhere of such a material or any rationale for making such a combination, as none of the references identify the benefit of restricting excessive tensile stress in the plantar fascia.

Additional claim limitations, including without a cushion layer (claims 75 – 80); single woven layer (claims 55, 73) are not disclosed by the prior art, nor would it be obvious to modify the disposable foot protector of Burgess to include the limitations. For example, Burgess teaches away from the idea of removing a cushion layer, as it would render the device of Burgess useless for protecting the sole of the foot. Further, the Examiner cursory dismissed the evidence of long felt need without an adequate or clearly stated rationale. The 1.132 affidavit was also dismissed as only being a single affidavit without considering the merits of that affidavit.

As discussed above, clearly the claims include critical limitations that are not disclosed by the cited references, nor would it be obvious to one skilled in the art to modify the cited references in the manner suggested to arrive at the Applicant's claimed inventions.

Respectfully submitted,

Date: September 15, 2009

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